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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,853	07/26/2001	Takafumi Ueno	12013/58002	7372

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KENYON & KENYON  
ONE BROADWAY  
NEW YORK, NY 10004

EXAMINER
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YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 04/09/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/915,853

Applicant(s)

UENO ET AL.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 January 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
- 4a) Of the above claim(s) 4,17,26,35,50-52 and 56-69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-16,18-25,27-34,36-49 and 53-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. The amendment filed 1/21/2003 (paper no. 9) is acknowledged and entered into the record. Accordingly, no new claims have been added, no claims have been canceled, or amended.
2. Claims 1-69 are pending. Claims 4,17,26,35,50-52, and 56-69 are withdrawn from consideration as being drawn to a non-elected subject matter. Applicant is reminded to cancel all claims that are drawn to non-elected subject matter.
3. Therefore, claims 1-3,5-16,18-25,27-34,36-49, and 53-55 are examined on the record.

#### ***Claim Rejections Maintained- 35 USC § 112, 2<sup>nd</sup> paragraph***

4. The rejection of claims 1-3,5-16,18-25,27-34,36-49, and 53-55 under 35 USC 112, 2<sup>nd</sup> paragraph is maintained for the reasons of record. Applicant's arguments have been carefully considered but are not found persuasive for the following reasons. With regard to claims reciting the term "regenerate", the scope of the claim reads on the re-supply of blood to damaged tissue. It is still not clear how the supply of blood to damaged tissue will regenerate, or make anew tissue that has been damaged. It would however, be clear to one of skill in the art that the supply of blood to damaged tissue would repair damaged tissue.
5. With regard to the term "effective", any amount that is added to some extent could be considered an effective amount, there is no limitation as to how much could be added to result in the desired effect.

***Claim Rejections Maintained- 35 USC § 112, 1<sup>st</sup> paragraph***

6. The rejection of claims 1-3,5-16,18-25,27-34,36-49, and 53-55 under 35 USC 112, 1<sup>st</sup> paragraph as lacking an enabling disclosure is maintained for the reasons of record. Applicant argues that the isolation EPC from the BM-MNCs is not essential to the practice of the invention and that the specification provides ample teaching so as to enable the invention. Applicant's argument has been carefully considered but is not found persuasive for the following reasons. Although the isolation of EPCs from BM-MNCs may not be critical for the invention to work, other factors have not been clearly taught so as to guide one of skill in the art to practice the full scope of the invention. Factors such as the addition of cytokines have not been addressed in the specification. As stated in the prior office action, cytokines play an important role in the formation of and or differentiation of BM-MNCs. Hamano *et al* disclose that BM-cells are positive for VEGF and bFGF and further speculate that the secretion of these growth factors ~~is~~<sup>are</sup> dependent on the tissue environment. Nowhere in the specification does it teach of specific administration to any specific tissue locations, wherein the administration would be high in local growth factor concentrations. As it is stated clearly in Hamano *et al*, induction of angiogenesis is dependent on the presence of growth factors. Furthermore, there are no specific limitations in the claims that would lead one of skill to administer the BM-MNCs to tissue areas that would induce growth factor secretion. And lastly, the specification has not taught the effects of BM-MNCs administration to areas that are not conducive to the differentiation of the BM-MNCs. As such, the skilled artisan has not been fully taught how to practice the invention because a multitude of

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factors have yet to be addressed. As such the skilled artisan is still forced into large quantities of experimentation to practice the instant invention.

***Claim Rejections Maintained - 35 USC § 102***

7. The rejection of claims 1-8, 10, 12-13, 15-16, 18-21, 23-28, 30, 32-34, 36-37, 39-40, 42, 44-45, 47-49, and 53-54 as being anticipated by Kobayashi *et al* is maintained for the reasons of record. Applicant argues that the reference does not anticipate the instant claims because Kobayashi *et al* do not recite the isolation of mononuclear cells from bone marrow. Applicant's arguments have been carefully considered but are not found persuasive. The Kobayashi *et al* reference does indeed teach the isolation of autologous bone marrow cells (see page 190 under Material and Methods- *Preparation of rat bone marrow cells*). Therefore, the recited limitations have been anticipated and the rejection is maintained.

***Claim Rejections Maintained- 35 USC § 102***

8. The rejection of claims 1-2, 5-8, 10-15, 18-21, 23-24, 27-30, 32-33, 36-37, 44-48, and 53-54 under 35 USC 102 (a) as being anticipated by Shintani *et al* is maintained for the reasons of record. Applicant argues that the elected species was heart muscle and that the art cited recites the administration of isolated BM-MNCs to skeletal muscle. Applicant's arguments have been carefully considered but are not found persuasive. Applicants elected heart muscle for prosecution on the merits, however, if no art is found on the species elected and others are present in claim that is presented in a Markush group, then art can be applied to any of the listed species. In the instant case, art was not found on cardiac tissue or heart muscle and therefore, art was applied to the

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next species listed, namely, skeletal muscle. Furthermore, the broad claim (i.e. claim 1) does not recite the limitation of heart muscle. The claims are therefore anticipated by the prior art.

### ***Conclusion***

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen

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April 7, 2003

*As*  
ALI R. SALIMI  
PRIMARY EXAMINER